

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED REVIEW STANDARDS FOR SURGICAL SERVICES

(By authority conferred on the Certificate of Need Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve the initiation, expansion, replacement, relocation, or acquisition of surgical services provided in a surgical facility.

(2) Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgical center, or a hospital licensed under Part 215 of the Code performing inpatient or outpatient surgical services are covered clinical services for purposes of Part 222 of the Code.

(3) A "freestanding surgical outpatient facility" is a health facility for purposes of Part 222 of the Code.

(4) The Department shall use sections 3, 4, 5, 6, 7, 8, and 10, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(5) The Department shall use Section 9, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(6)(a) These standards shall apply to the review of all Certificate of Need applications for surgical services for which the Director of the Department of Community Health has not made a final decision under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws, as of the effective date of these standards.

(b) In the case of an application which has been deemed submitted, but which has not received a final decision by the Director on the effective date of these standards, an applicant may request, and the Department shall grant, an extension of up to 60 days to the Director's decision date established under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws. This period shall be used for the submission and review of any information which may be necessary to show compliance with these standards. The Department shall consider this information before a final decision is made.

(c) If a final decision reverses a proposed decision approving the project, the administrative hearing provisions of Section 22231(8), being Section 333.22231(8) of the Michigan Compiled Laws, shall apply. If the proposed decision was a denial and an administrative hearing has been held, the Director shall permit a rehearing or continuation of the hearing in order to consider information submitted under this subsection, and shall consider the results of that hearing before a final decision is made.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of a surgical service" means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service.

(b) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416, that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(c) "Burn care," for purposes of these standards, means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 ~~et seq.~~ of the Michigan Compiled Laws.

(e) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(f) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(g) "Department" means the Michigan Department of Community Health.

(h) "Emergency Room," for purposes of Section 6(2)(b) of these standards only, means a designated area in a licensed hospital and recognized by the Department of Consumer and Industry Services as having met the staffing and equipment requirements for the treatment of emergency patients.

(i) "Endoscopy" means visual inspection of any cavity of the body by means of an endoscope.

(j) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.

(k) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is licensed as part of a licensed hospital site or a freestanding surgical outpatient facility, or that is certified as an ambulatory surgical center.

(l) "Expand a surgical service" means the addition of one or more operating rooms at an existing surgical service.

(m) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned by, operated, and licensed as a part of a hospital at a licensed hospital site.

(n) "Hospital" means a health facility licensed under Part 215 of the Code.

(o) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to provide surgical services. It is the time from when a patient enters an operating room until that same patient leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any time a patient spends in pre- or post-operative areas including a recovery room.

(p) "Initiate a surgical service" means to begin operation of a surgical facility at a site that does not perform surgical services as of the date an application is submitted to the Department. The term does not include the relocation of a surgical service or one or more operating rooms meeting the requirements of Section 7.

(q) "Licensed hospital site" means either:

(i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(r) "Offer" means to perform surgical services.

(s) "Operating room" or "OR," for purposes of these standards, means a room in a surgical facility constructed and equipped to perform surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used exclusively for endoscopy or cystoscopy cases.

(t) "Operating suite," for purposes of these standards, means an area in a surgical facility that is dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision of surgery.

(u) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to a hospital for an overnight stay is not anticipated as being medically necessary.

(v) "Relocate a surgical service or one or more operating rooms" means changing the geographic location of an existing surgical facility or one or more operating rooms to a different site within the relocation zone.

(w) "Relocation zone," for purposes of these standards, means a site that is within a 10-mile radius of the site at which an existing surgical service is located if an existing surgical service is located in a nonrural county, or a 20-mile radius if an existing surgical service is located in a rural county.

(x) "Renovate an existing surgical service or one or more operating rooms" means a project that:

(i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or ASC;

(ii) does not involve new construction;

(iii) does not involve a change in the physical location within the surgical facility at the same site; and

(iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

Renovation of an existing surgical service or one or more operating rooms may involve a change in the number of square feet allocated to an operating suite. The renovation of an existing surgical service or one or more operating rooms shall not be considered the initiation, expansion, replacement, relocation, or acquisition of a surgical service or one or more operating rooms.

(y) "Replace a surgical service or one or more operating rooms" means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms currently operated by an applicant at the same site as the operating room(s) to be replaced. The term does not include the renovation of an existing surgical service or one or more operating rooms.

(z) "Rural county" means a county not located in a metropolitan area as that term is defined pursuant to the "Revised standards for defining metropolitan areas in the 1990's" by the Statistical Policy Office of the Office of Information and Regulatory Affairs of the United States Office of Management and Budget, 55 F.R. p. 12154 (March 30, 1990).

(aa) "Sterile corridor," for purposes of these standards, means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses, laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

(bb) "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

(cc) "Surgical facility" means either:

(i) a licensed freestanding surgical outpatient facility;

(ii) a certified ambulatory surgical center; or

(iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

(dd) "Surgical service" means performing surgery in a surgical facility.

(ee) "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I or II trauma center, or equivalent standards.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements

Sec. 3. (1) The Department shall use the number of operating rooms pursuant to subsection (2) and the number of surgical cases, or hours of use, as applicable, pursuant to subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set forth in the applicable sections of these standards.

(2) The number of operating rooms for each type of surgical facility shall be determined as follows:

(a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

(i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily for obstetrical services.

(ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

(iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter shall not be considered as an operating room.

(iv) An operating room that is or will be used exclusively to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 1 burn care and 1 trauma care operating room shall be excluded pursuant to this subdivision.

(v) An operating room that is or will be used, though not exclusively, to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision.

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms in which endoscopy or cystoscopy cases are or will be performed.

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy or cystoscopy cases.

(3) The number of surgical cases, or hours of use, shall be determined as follows:

(a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms, including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(v), but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection (2)(a)(i), (ii), (iii), and (iv).

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall be excluded.

Section 4. Requirements for approval for applicants proposing to initiate a surgical service

Sec. 4. (1) An applicant proposing to initiate a surgical service shall demonstrate that each proposed operating room shall perform an average of at least 1,200 surgical cases per year per operating room in the second 12 months of operation, and annually thereafter.

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural county that does not offer surgical services as of the date an application is submitted to the Department.

(3) If the number of surgical cases projected under subsection (1) includes surgical cases performed at an existing surgical facility(s), an applicant shall demonstrate that it meets the requirements of Section 10(2).

Section 5. Requirements for approval for surgical services proposing to expand an existing surgical service

Sec. 5. (1) An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following:

(a) all existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,200 surgical cases or

(ii) in a hospital, 1,600 hours of use or in an FSOF or ASC, 1,800 hours of use per year per operating room for the most recent 12-month period for which verifiable data is available to the Department.

(b) All operating rooms, existing and proposed, are projected to perform an average of at least:

- (i) 1,200 surgical cases or
- (ii) in a hospital, 1,600 hours of use or in an FSOF OR ASC, 1,800 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(2) Subsection (1) shall not apply if the proposed project involves adding a second operating room in a licensed hospital site located in a rural county that currently has only one operating room.

(3) If the number of surgical cases, or hours of use, projected under subsection (1) includes surgical cases, or hours of use, performed at an existing surgical facility(s), an applicant shall demonstrate that it meets the requirements of Section 10(2).

Section 6. Requirements for approval for facilities proposing to replace a surgical service or one or more operating rooms

Sec. 6. (1) An applicant proposing to replace an existing surgical service or one or more operating rooms at the same site shall demonstrate each of the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

- (i) 1,200 surgical cases or
- (ii) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room for the most recent 12-month period for which verifiable data is available to the Department.

(b) All operating rooms, existing and proposed, are projected to perform an average of at least:

- (i) 1,200 surgical cases or
- (ii) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(2)(a) Subsection (1) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site, if the surgical facility is located in a rural county and has one or two operating rooms.

(b) Subsection (1) shall not apply if the proposed project involves replacing one or two operating rooms at the same licensed hospital site if the surgical facility is a hospital that:

- (i) is located in a nonrural county;
- (ii) has an emergency room at the same licensed hospital site as the operating rooms;
- (iii) has exactly two operating rooms; and
- (iv) has performed at least 1,200 surgical cases, or at least 1,600 hours of use, per year for the most recent 12-month period for which verifiable data is available to the Department.

Section 7. Requirements for approval for applicants proposing to relocate a surgical service or one or more operating rooms

Sec. 7. An applicant proposing to relocate a surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(1) The proposed relocation will not result in an increase in the total number of operating rooms operated by an applicant at the existing and proposed sites unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The proposed new site is located within the relocation zone.

(3) All existing operating rooms in the surgical facility to be relocated have performed an average of at least:

- (a) 1,200 surgical cases or
- (b) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room for the most recent 12-month period for which verifiable data is available to the Department.

(4) All operating rooms, existing and proposed, are projected to perform an average of at least:

- (a) 1,200 surgical cases or
- (b) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(5) If the number of surgical cases projected under subsection (4) includes surgical cases, or hours of use, performed at an existing surgical facility(s), an applicant shall demonstrate that it meets the requirements of Section 10(2).

Section 8. Requirements for approval for applicants proposing to acquire an existing surgical service

Sec. 8. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable:

(1) The acquisition will not result in an increase in the number of operating rooms at the surgical service to be acquired unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The location of the surgical service does not change as a result of the acquisition unless an applicant can demonstrate compliance with the applicable requirements of Section 7.

(3) An applicant agrees and assures to comply with all applicable project delivery requirements.

(4) For the first application for proposed acquisition of an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, an existing surgical service to be acquired shall not be required to be in compliance with the volume requirements applicable to the seller/lessor on the date the acquisition occurs. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition, and annually thereafter.

(5) For any application for proposed acquisition of an existing surgical service except the first application, for which a final decision has not been issued, after the effective date of these standards, an applicant shall be required to document compliance with the volume requirements applicable to the existing surgical service on the date an application is submitted to the Department.

(6) Subsection (5) shall not apply if the proposed project involves the acquisition of both of the operating rooms of an existing surgical service of a hospital if the hospital from which the service being acquired is: (A) located in a nonrural county, (b) has an emergency room at the same licensed hospital site as the operating rooms, (c) has exactly two operating rooms, and (d) has performed at least 1,200 surgical cases or at least 1,600 hours of use per year for the most recent 12-month period for which verifiable data is available to the department. The operating rooms acquired under this subsection must remain part of a surgical service of a licensed hospital.

Section 9. Project delivery requirements -- terms of approval for all applicants

Sec. 9. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of Certificate of Need approval:

- (a) Compliance with these standards.
- (b) Compliance with applicable operating standards.
- (c) Compliance with the following terms of approval, as applicable:
 - (i) The approved services and/or operating rooms shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

- (A) not deny surgical services to any individual based on ability to pay or source of payment;
- (B) provide surgical services to any individual based on the clinical indications of need for the service.
- (C) maintain information by payer and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iii) An applicant shall participate in a data collection network established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified site, in a format established by the department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(iv) Within 10 days after initiation of the service, an applicant shall provide the Department with a notice stating the first date on which the approved service was initiated.

(d) Compliance with the following quality assurance standards, as applicable:

(i) Surgical facilities shall have established policies for the selection of patients and delineate procedures which may be performed in that particular facility.

(ii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including cardiopulmonary resuscitation.

(iii) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of patients when necessary. All surgeons who perform surgery within the facility shall have evidence of admitting privileges or of written arrangements with other physicians for patient admissions at a local hospital. The surgical facility shall have an established procedure, including a transfer agreement, that provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the surgical facility to a hospital that is capable of providing the necessary inpatient services and is located within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an applicant shall have a transfer agreement with the nearest hospital having such capability.

(iv) An applicant shall have written policies and procedures regarding the administration of a surgical facility.

(v) An applicant shall have written position descriptions which include minimum education, licensing, or certification requirements for all personnel employed at the surgical facility.

(vi) An applicant shall have a process for credentialing individuals authorized to perform surgery or provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, or dentistry.

(vii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including biologicals) services, either on-site or through contractual arrangements.

(viii) An applicant shall have written policies and procedures for advising patients of their rights.

(ix) An applicant shall develop and maintain a system for the collection, storage, and use of patient records.

(x) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

(xi) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility shall incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.

(e) For purposes of evaluating subsection (d), the Department shall consider it *prima facie* evidence as to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.

(2) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA

368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(3) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 10. Documentation of projections

Sec. 10. (1) An applicant required to project volumes of service under the applicable sections of these standards shall specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

(2) If a projected number of surgical cases, or hours of use, includes surgical cases, or hours of use, performed at an existing surgical facility(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in compliance with the volume requirements applicable to that facility, and will be in compliance with the volume requirements applicable to that facility subsequent to the initiation, expansion, or relocation of the surgical services proposed by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) The name of each physician that performed surgical cases to be transferred to the applicant surgical facility.

(b) The number of surgical cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.

(c) The location(s) at which the surgical cases to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.

(d) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3 years subsequent to the initiation, expansion, or relocation of the surgical service proposed by an applicant.

(e) The number of surgical cases performed, at the existing surgical facility from which surgical cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of use in documenting compliance with the applicable sections of these standards, if an applicant provides documentation, satisfactory to the Department, from the surgical facility from which the hours of use are being transferred.

Section 11. Effect on prior Certificate of Need review standards; comparative reviews

Sec. 11. (1) These Certificate of Need review standards supercede and replace the Certificate of Need Review Standards for Surgical Facilities approved by the Certificate of Need Commission on December 12, 1995 and effective on January 27, 1996.

(2) Projects reviewed under these standards shall not be subject to comparative review.